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Equal Opportunity in Employment and Services

North Dakota Department of Agriculture Pesticide Registration and Exemption Guidelines (5/1/2009)

Background

The North Dakota Department of Agriculture is committed to ensuring human safety and protecting the environment through the proper use of pesticides. In addition, the Department acknowledges the critical role that pesticides play in producing high quality food and controlling economically important pests. Therefore, the Department uses its statutory authority to regulate the registration, distribution, sale, and proper use of pesticide products.

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FIFRA Section 3 Registrations

Pesticide registration is described in Chapter 19-18 of the North Dakota Century Code (N.D.C.C.). All pesticides must be registered with the North Dakota Department of Agriculture or exempted from registration prior to their distribution, sale, offering for sale, transport, or use in the state.

Each pesticide registration covers a designated two-year period beginning January first of every even-numbered year and expiring December thirty-first of the following year. Prior to receiving a registration, the applicant must provide the information and documentation described in Section 19-18-04 of the North Dakota Century Code. Product labels are reviewed for content to ensure that they meet federal and state requirements.

Each pesticide registration application must include:

- A. A completed Application for Registration of Pesticides (SFN 17175)
- B. A copy of the product labeling
- C. A Material Safety Data Sheet (MSDS)
- D. Pesticide registration fee (\$350 per product)

The North Dakota Department of Agriculture has entered into a relationship with Kelly Registration Systems (KRS) to streamline our pesticide registration processes and provide a more efficient electronic document management platform. Registrants can use KRS to submit pesticide registration applications and supporting documents online, both for registration renewals and new product registrations through a registration platform called KSAMS. Registrants are strongly encouraged to use the KSAMS registration option. KRS assigns usernames and passwords to access the system. You may request a username and password by contacting KRS at 1-800-803-5777 or via email at support@krsnetwork.com.

Please note that the Department **no longer accepts hard-copy pesticide labeling and Material Safety Data Sheets**. The preferred method for registrants to submit electronic documents is through the KRS system. If that is not an option, registrants can submit electronic documents to the Department in portable document format (pdf) via email at reg@nd.gov or on a compact disc.

FIFRA Section 25(b) Products

Section 25(b) products are characterized as minimum risk pesticides by EPA and are exempt from EPA registration. N.D.C.C. 19-18 allows that manufacturers of minimum risk FIFRA Section 25(b) pesticides may apply to the Department for an exemption from registration (see FIFRA Section 25(b) Registration Exemptions section). All minimum risk FIFRA Section 25(b) pesticides must be either registered or exempted from registration prior to their distribution, sale, offering for sale, transport, and use in North Dakota. Therefore, if the manufacturer declines an exemption from registration, the product(s) must be registered as pesticides. Labels of Section 25(b) products are thoroughly reviewed to ensure that they meet the requirements of EPA PR Notice 2000-6.

Supplemental Distributor Registrations

Supplemental distributor registrations are characterized as having a three-part EPA Registration Number such as XXXX-XXX-XXXX, where the left-most number indicates the primary registrant company number, the middle number indicates the product number, and the right-most number indicates the supplemental distributor company number. EPA does not review labels of products with supplemental distributor registration numbers. Therefore, the North Dakota Department of Agriculture reviews supplemental distributor product labels to ensure that use directions do not differ from those in the EPA-stamped label. Consistent with EPA policy, the Department allows for the use directions on the supplemental distributor label to contain more restrictive directions or fewer uses than the EPA stamped label. However, use directions on supplemental distributor labels cannot expand the uses allowed on the EPA-stamped label.

Pesticide Devices

The North Dakota Century Code does not require the registration of pesticide devices. Therefore, the North Dakota Department of Agriculture does not register simple mechanical pesticide devices as long as:

1. The product meets the definition of “device” in Section 19-18-02 of the North Dakota Century Code.
2. The pesticidal action of the product is a result of mechanical or physical destruction of the pest.
3. The product does not contain any chemical substance for which pesticidal claims are made.

The Department considers such things as rodent traps, sticky traps, flyswatters, water filters, and similar simple mechanical devices to be pesticide devices.

Co-Packs

Many products are distributed and sold as co-packs with two or more components packaged together with the intent that the components will be mixed by the user. Often the co-pack components are registered pesticides themselves. The Department requires each component of a co-pack product to be registered separately. If the co-pack product itself has its own product name and it has its own EPA Registration Number, it will also be required to be registered.

Discontinuance

N.D.C.C. 19-18-04 requires that all pesticide registrations go through a two-year discontinuance period to clear all outstanding products from the channels of trade. Since pesticide registrations are issued for designated two-year periods, registration of a discontinued pesticide must be maintained for at least one full registration period. Registrants seeking discontinuance of any registrations are asked to notify the Department during the registration renewal process so that the request can be documented.

Company or Product Name Changes

The Department is contacted frequently by registrants to update our registration records to reflect changes to a company or product name. This raises questions as to whether these changes require a new product registration. It also raises questions on whether or not existing product in the channels of trade is registered and compliant with N.D.C.C. 19-18.

N.D.C.C. 19-18-04 states that a certificate of registration is not transferable from one person to another, or from the ownership to whom issued to another ownership. Significant changes to either the: A) product name, B) EPA Registration Number, or C) company name will require new registration, and existing product(s) in the channels of trade will need to go through the necessary discontinuance period. Minor changes to the name of the company that are not reflected in significant changes to the product name or EPA Registration Number can be handled through updates to the Department's registration records. The Department will use its discretion to determine when changes to the company or product name are significant enough to justify new registrations.

FIFRA Section 25(b) Registration Exemptions

Certain pesticide products are exempt from EPA registration because they are classified as minimum risk pesticides under FIFRA Section 25(b). Some manufacturers of minimum risk pesticides have expressed concern that classifying their product(s) as "pesticides" could negatively impact their markets. Therefore, N.D.C.C. 19-18 was amended in 2005 to allow manufacturers of minimum risk FIFRA Section 25(b) pesticides to apply for an exemption from pesticide registration. An exemption from registration can be issued in lieu of a pesticide registration. However, it should be noted that all minimum risk pesticides must either be registered or exempted from registration prior to their sale, offering for sale, distribution, and use in North Dakota.

Each exemption from registration covers a designated two-year period beginning January first of every even-numbered year and expiring December thirty-first of the following year. Prior to receiving an exemption from registration, the applicant must provide the information and documentation described in Section 19-18-13 of the North Dakota Century Code. Labels of Section 25(b) products are thoroughly reviewed to ensure that they meet the requirements of EPA PR Notice 2000-6.

Each application for exemption from registration must include the following:

- A. A completed Application for Exemption from Registration of Pesticides (SFN 54343)
- B. A copy of the product labeling
- C. Exemption from pesticide registration fee (\$350 per product)

Please note that the preferred format of all pesticide labels is portable document format (pdf) submitted on a compact disc. If electronic versions of labels are not available, applicants are asked to submit original, color hard copies of sufficient quality to scan.

FIFRA Section 24(c) Registrations

The North Dakota Department of Agriculture encourages the use of Section 24(c) registrations to address special local needs. The Department uses Section 24(c) authority consistent with the publication “Guidance on FIFRA §24(c) Registrations” prepared by EPA on February 9, 1996.

Prior to granting a Section 24(c) registration, the Department must:

1. Obtain the consent of the product registrant.
2. Verify that a special local need exists, consistent with the EPA guidelines described above.
3. If the treated crop is to be used for food or feed, verify that the desired use is covered under existing permanent tolerances.
4. If the treated crop is to be used for food or feed, verify that the intended use pattern will not cause pesticide residues to exceed set tolerances. Pesticide residue data or a sound scientific argument from the registrant is required to make this determination.
5. Complete EPA form 8570-25, “Application for/Notification of State Registration of a Pesticide to Meet a Special Local Need”.
6. Approve supplemental labeling from the registrant allowing for the desired use.
7. Verify that the product is registered with the Department.

All pesticides covered under FIFRA Section 24(c) registrations must be registered or exempted from registration with the North Dakota Department of Agriculture consistent with Chapter 19-18 of the North Dakota Century Code. However, separate registration or exemption from registration fees are not charged for Section 24(c) registrations.

Consistent with federal requirements, the North Dakota Department of Agriculture will notify the EPA of all Section 24(c) registrations within ten (10) days of their issuance. The notification package will consist of a cover letter describing the special local need and containing the assigned Section 24(c) Registration Number, a completed EPA form 8570-25, a copy of the approved supplemental labeling, any supporting data, and applicable letters of support.

Section 24(c) registrations are typically given an expiration date to allow a maximum of five (5) years of use. Ninety (90) days prior to the expiration date, the holder of the Section 24(c) registration will be contacted to determine whether they still support the Section 24(c) registration. The Department will also use this time to verify that a special local need still exists. If the registrant no longer supports the registration or a special local need no longer exists, the

registration will expire on the expiration date. If the registrant supports the registration and the Department determines that a special local need still exists, a new Section 24(c) registration will be granted to allow an additional period of use up to five (5) years from the date that the new registration takes effect.

“Me-too” Section 24(c) Registrations

The North Dakota Department of Agriculture supports multiple product registrations, within reason, to address special local needs. Therefore, in an effort to give North Dakota farmers as many pest management options as possible, the Department will issue multiple Section 24(c) registrations for competing products to address the same special local need if each registration request is supported with necessary data. To prevent abuse of the “me-too” provision, the Department will limit a registrant to one Section 24(c) registration to address a given special local need.

FIFRA Section 18 Exemptions

The North Dakota Department of Agriculture supports the responsible use of Section 18 exemptions to address emergency pest situations. The Department does not support the use of Section 18 exemptions as a means to simply gain use of a product prior to EPA granting a registration for the desired use. The Department considers a situation to be an emergency only if it meets EPA’s criteria of being “urgent” and “non-routine”.

The Department encourages commodity groups and growers to request Section 18 exemptions as early as possible in order for the Department to prepare a high-quality request package. Prior to submitting a Section 18 exemption request, the Department must verify that:

1. The situation meets the definitions of urgent and non-routine.
2. No effective pesticides are registered for control of the pest(s) under the emergency conditions.
3. No economically or environmentally feasible alternative control practices (including non-chemical control practices) are available.
4. The situation involves the introduction of a new or not previously prevalent pest, or will present significant risk to human health or the environment, or will cause significant economic loss.
5. Adequate progress has been made toward obtaining a Section 3 or 24(c) registration for the desired use if the request is a repeat request.

If, in the Department’s opinion, a situation does not meet the criteria above, the Department will reject the Section 18 exemption request and notify the requestor of any data deficiencies within

twenty-one (21) days of the receipt of the request. If additional data is provided after that time, the Department will re-evaluate whether the situation meets the criteria above.

If the situation meets the criteria described above, the Department will prepare a Section 18 exemption request document with supporting data. The Department will forward a copy of the Section 18 request document and the proposed use directions to the North Dakota Game and Fish Department, North Dakota Department of Health, and the local office of the Fish and Wildlife Service. These agencies will have a minimum of seven (7) days to provide comment on the request. Changes to the exemption use directions or request document based on these comments will be made at the Department's discretion. However, all comments from these partner agencies will be forwarded to EPA. If time constraints do not allow for the receipt of comments from the partner agencies above, the Department will send the Section 18 exemption request package to EPA, notify partner agencies of the submission, and forward any comments to EPA.

The Section 18 exemption request package submitted to EPA includes the following:

1. Section 18 exemption request document with documentation that the situation meets the criteria above.
2. Letter of support from the registrant or manufacturer of the pesticide.
3. Copy of the proposed exemption use directions.
4. Letter of support from appropriate NDSU extension personnel

If the exemption request is a repeat request, one (1) copy of the request package is submitted to EPA. If the exemption request is a new request, the Department will submit three (3) copies of the request package.

When possible, Department will work with other neighboring state lead agencies to prepare joint Section 18 request packages.

Crisis exemptions

Crisis exemptions are reserved for those occasions in which an unforeseen emergency pest outbreak occurs with little or no warning. The Department will only declare a crisis exemption after notifying EPA of the Department's intended actions. If the crop is to be used as a feed or food source, the Department must determine that the intended use is covered under existing permanent or time-limited tolerances. If tolerances do not exist, the Department must obtain confirmation from EPA that the Agency will be able to set a permanent or time-limited tolerance by harvest time.

FIFRA Section 2(ee) Recommendations

The North Dakota Department of Agriculture considers 2(ee) recommendations to be advertising, not pesticide labeling. The Department neither officially approves nor disapproves 2(ee) recommendations. However, the Department reviews 2(ee) recommendations to ensure that use directions do not conflict with those on the full Section 3 labeling for the product(s) described in the recommendation. Section 2(ee) recommendations are filed and kept for a minimum of one (1) year from the date of receipt.

Experimental Use Permits (EUPs)

The North Dakota Department of Agriculture encourages registrants to develop pesticides and pesticide use patterns to provide North Dakota growers and ranchers with reliable, economical, and effective pest control tools. Therefore, the Department recognizes the importance of experimental research and the use of Experimental Use Permits (EUPs). The Department does not have the authority to issue EUPs under state law. Therefore, parties wanting to use a pesticide under an EUP are asked to contact the U.S. EPA for a permit. As a courtesy, holders of EUPs are asked to notify the Department at least 48 hours prior to use of a pesticide under an EUP. Pesticides used and distributed in North Dakota solely under Experimental Use Permits are exempt from registration per N.D.C.C. 19-18-07.

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